

PHSA Laboratories

BCCDC Public Health Laboratory

November 24, 2021

RE: 2021/2022 SARS-CoV-2 Laboratory Testing Updates

SARS-CoV-2 (COVID-19) nucleic acid testing (NAT) will continue to be performed on all specimens submitted from clients (outpatients and inpatients) with compatible symptoms, contacts of those infected, and when requested by the MHO.

NAT Interpretation Guidelines for the BCCDC PHL lab-developed test

In November 2021, the BCCDC Public Health Laboratory (PHL) will modify the cycle threshold (Ct) cut-off value used to identify positive COVID-19 cases by the lab-developed NAT, from 38 to 35. Ct values for a NAT test refer to the number of cycles of amplification that are required for nucleic acid product detection. Typically, during NAT a sample will undergo 40 amplification cycles. Ct values correlate inversely with the viral load (the lower the Ct value, the higher the viral load). However, Ct values and the corresponding viral loads are affected by sample quality and the time of sample collection relative to onset of symptoms. Further, the Ct value generated will differ by testing platforms/technologies.

Currently, a Ct cut-off of 38 is used to report positive SARS-CoV-2 results for the BCCDC PHL lab-developed NAT: nucleic acid products detected with $Ct \leq 38$ are reported as positive (COVID-19 virus DETECTED by NAT), while nucleic acid products detected between $Ct > 38$ and 40 are reported as indeterminate (Clinical correlation is required, recollection of the sample may be indicated). If nucleic acid products are not detected within 40 cycles, the test is reported as negative.

Starting on November 24, a new cut-off of 35 will be adopted to differentiate between positive and indeterminate SARS-CoV-2 results for the BCCDC PHL lab-developed NAT:

- nucleic acid products detected with $Ct \leq 35$ will be reported as positive (COVID-19 virus DETECTED by NAT),
- nucleic acid products detected between $Ct > 35$ and 40 will be reported as indeterminate (Clinical correlation is required, recollect sample if clinically indicated),
- If nucleic acid products are not detected within 40 cycles, the test will be reported as negative.

Ct cut-offs for identification of positive cases are based on test performance and a Ct cut-off of 35 is standard for most NATs. A Ct cut-off of 38 was adopted during SARS-CoV-2 emergence, but based on recent testing at the BCCDC PHL using lab-developed test, very few nucleic acid products are detected within the 35 to 38 Ct range: this year from mid-July to mid-October 2203 (8.5%) samples had detectable nucleic acid product with $Ct \leq 35$, while 96 (0.4%) samples had detectable nucleic acid product between $Ct > 35$ and 38 and 54 (0.2%) samples had detectable nucleic acid product between > 38 and 40. The BCCDC PHL lab-developed NAT is the most commonly used test for the detection of SARS-CoV-2 infection at the BCCDC.

Specimen and Requisition Requirements

Starting December 6/2021, the BCCDC Public Health Laboratory (PHL) will no longer accept Hologic Aptima swabs for SARS-CoV-2 NAT testing. The preferred samples for SARS-CoV-2 NAT testing are nasopharyngeal (NP) swabs and saline gargles. Collection kits with Universal Transport Medium (UTM) and flocked swabs, such as YOCON or COPAN collection kits, are preferred for identification of SARS-CoV-2 from NP samples by NAT.

At the time of a swab shortage during the early COVID-19 pandemic waves, the BCCDC PHL validated the use of Hologic Aptima® Unisex and Multi-test swab collection kits for the SARS-CoV-2 NAT testing. However, these Hologic Aptima collection kits are not designed for NP collection and are not optimal for SARS-CoV-2 detection. They were intended to serve as a short-term solution due to swab shortages. Furthermore, a preliminary stability study at the PHL revealed that YOCON collection kits are able to detect SARS-CoV-2 nucleic acid by NAT over a period of 7 days at elevated temperatures (30°C).

Since we now have an adequate inventory of YOCON collection kits, we require that clinics and collection sites discontinue use of the Hologic Aptima® Unisex and Multi-test swabs for the collection of NP samples for SARS-CoV-2 NAT testing. As such, we have stopped the distribution of these Hologic Aptima collection kits for this purpose.

We will continue to accept Hologic Aptima swabs for SARS-CoV-2 NAT testing until December 5/2021, to allow time for clinics to transition to the preferred x swabs for sample collection. Starting on December 6/2021, the BCCDC PHL will no longer accept Hologic Aptima swabs for SARS-CoV-2 NAT testing and samples will be rejected.

Please note that Hologic Aptima Unisex and Multi-test collection kits are still the appropriate kits to use for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing.

See Appendix 1 for pictures of acceptable and unacceptable swab kits for SARS-CoV-2 NAT.

Notably, YOCON Virus Sampling Kits have an extended shelf life of 24 months beyond the expiry date per a Health Canada Interim Order (Appendix 2).

For other testing details, please refer to the BCCDC Public Health Laboratory test menu on eLab: <http://www.elabhandbook.info/phsa/>.

Sincerely,



Mel Krajden, MD, FRCPC
Public Health Laboratory Director
BC Centre for Disease Control

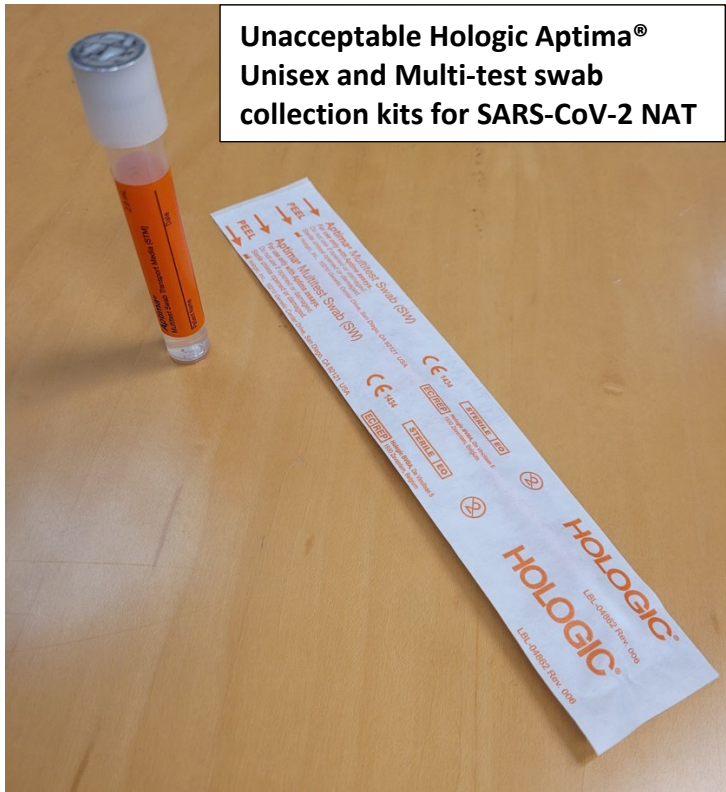
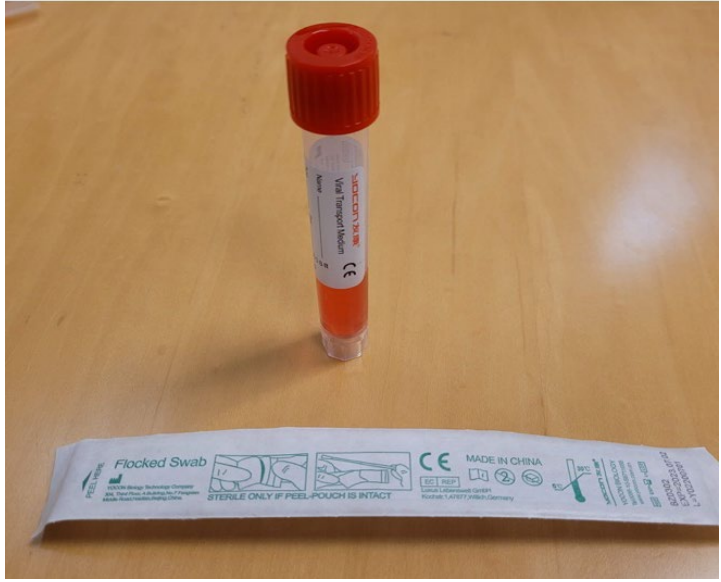
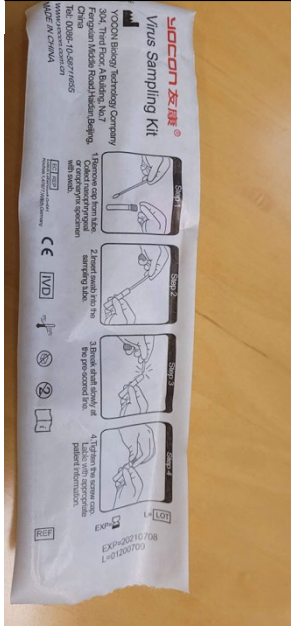


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Appendix 1.



Acceptable Yocon (pictured) or COPAN Collection kits with Universal Transport Medium (UTM) and flocked swabs for SARS-CoV-2 NAT



Unacceptable Hologic Aptima® Unisex and Multi-test swab collection kits for SARS-CoV-2 NAT



DATE: November 18, 2021

***** Revised *****

PRODUCT: Kit, Virus Sampling, Yocon, Bio Nuclear Diagnostics (BND)

***** ADVISORY - DO NOT REMOVE PRODUCTS *****

Who is Impacted: FHA IHA NHA PHC PHSA VCH VIHA

Specific sites/units: See attached usage spreadsheet.

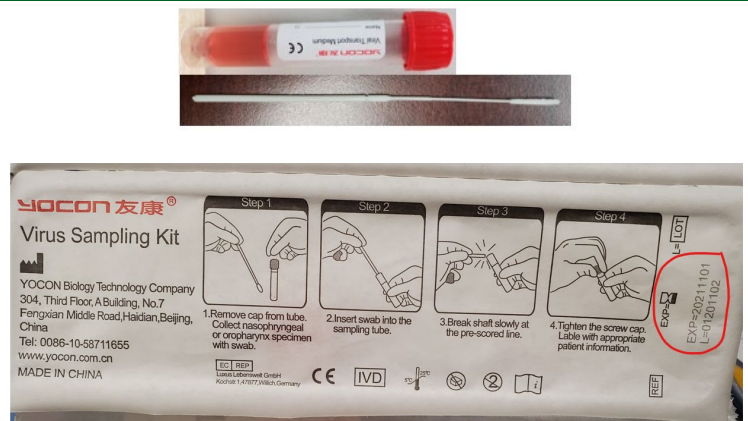
BACKGROUND: BND has issued a recall advisory for the Yocon Virus Sampling Kit with expiry dates for 2021 or earlier as there are updated Instructions for Use (IFU) and a Health Canada Interim Order to extend the shelf life of the product to 24 months beyond the manufacture date. Previously the shelf life was 12 months as per the expiry date on the package.

ACTIONS:

- **Do Not Remove Product.**
- Review your inventory for Yocon Virus Sampling Kits (product code **STC-110**) with an expiry date of **2021 or earlier**. Expiry date is no longer as noted on the package but it is extended by 12 months. The expiration is found on the outer package of the collection kit.
 - Refer to the top of page 2 in the attached updated IFU where the period of validity has been extended for 24 months beyond the manufacture date.
 - See attached Health Canada Interim Order approving this change to the expiry date.
 - **Note:** Packaging expiry date will not be relabelled.

**Virus Sampling Kit, Yocon
BND STC-110**

Health Authority Order #	Inventory	
FHA # 485955	<input checked="" type="checkbox"/> Inventory	<input type="checkbox"/> Non-Stock
IHA # 1065213	<input checked="" type="checkbox"/> Inventory	<input type="checkbox"/> Non-Stock
NHA # 5007145	<input checked="" type="checkbox"/> Inventory	<input type="checkbox"/> Non-Stock
PHC # 00128999	<input checked="" type="checkbox"/> Inventory	<input type="checkbox"/> Non-Stock
PHSA # 00094948	<input checked="" type="checkbox"/> Inventory	<input type="checkbox"/> Non-Stock
VCH # 00128999	<input checked="" type="checkbox"/> Inventory	<input type="checkbox"/> Non-Stock
VIHA # 0126202	<input checked="" type="checkbox"/> Inventory	<input type="checkbox"/> Non-Stock



If you have any questions regarding the above recall, please contact:

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